

Remarks:

The above amendments and these remarks are responsive to the Office action dated September 21, 2005.

Prior to entry of this Amendment, claims 1-24 remained pending in the application. However, in the Office action, the Examiner considered only claims 1-7, claims 8-24 having been withdrawn pursuant to an earlier restriction/election requirement. Applicants hereby confirm the earlier provisional election of claims 1-7 (Invention I), and thus cancel claims 8-24 without prejudice.

Claims 1-2 and 4-7 stand rejected under 35 U.S.C. §102(b) based on Voss et al. (US 4,322,449). Claim 3 stands rejected under 35 U.S.C. §103(a) based on Voss et al. in view of Voges (US 6,894,841). Applicants respectfully traverse these rejections for the reasons set forth below.

In view of the amendments above, and the remarks below, applicants respectfully request reconsideration of the application under 37 C.F.R. § 1.111 and allowance of the pending claims.

Rejections under 35 USC § 102

As noted, claims 1-3 and 6-8 stand rejected under 35 U.S.C. §102(b) based on Voss et al. Voss et al. discloses a method for the preparation of pharmaceuticals using a piezoelectric dosing system to dot liquid, dissolved or suspended active substance onto a pharmaceutical carrier. Voss et al. does not disclose any selection of a desired dot topography, or of any basis for making such a selection. In fact, Voss et al. does not even consider any relationship between dot topography and dissolution rate of the active substance.

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Claim 1 recites:

1. (Original) A method of controlling a dissolution rate of a bioactive agent, the method comprising:
selecting a desired dot topography corresponding to a target dissolution rate;
applying a bioactive agent to a delivery substrate to form dots having the desired dot topography on the delivery substrate.

Claim 1 thus expressly recites that "selecting a desired dot topography corresponding to a target dissolution rate." As noted, Voss et al. does not even consider a target dissolution rate, much less select a desired dot topography based on target dissolution rate. In fact, Voss et al. does not even consider dot topography, or the ability to apply dots having a desired dot topography.

The Examiner asserts only that Voss teaches control of "various parameters," none of which are "dot topography". Furthermore, although the Examiner asserts that control of the indicated parameters inherently provide control over dissolution rate (an assertion that applicants disagree with), the Examiner does not indicate any disclosure or suggestion of selecting dot topography to achieve a target dissolution rate. In fact, Voss et al. fails to even recognize any relationship between dot topography and dissolution rate.

For at least the foregoing reasons, Voss et al. does not anticipate claim 1, and the rejection of claim 1 under 35 U.S.C. §102(b) based on Voss et al. should be withdrawn. Claims 2 and 4-7 depend from claim 1, and are distinguishable for at least the same reasons as claim 1.

Rejections under 35 USC § 103

Claim 3 stands rejected under 35 U.S.C. §103(a) based on Voss et al. in view of Voges. As noted above, Voss et al. discloses a method for the preparation of pharmaceuticals using a piezoelectric dosing system to dot liquid, dissolved or

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suspended active substance onto a pharmaceutical carrier. Voges discloses an inhaler-type dispenser of a physiologically active substance using either a piezoelectric ejection device or a thermal "bubble jet" ejection device. As described, the Voges dispenser includes a mouthpiece for use in applying the physiologically active substance directly to the user.

Neither reference discloses or suggests "selecting a desired dot topography corresponding to a target dissolution rate" as recited in claim 1 (from which claim 3 depends). Claim 3 thus is distinguished from Voss et al. and Voges for at least the same reasons as set forth with respect to claim 1. Accordingly, the rejection of claim 3 under 35 U.S.C. §103(a) based on Voss et al. in view of Voges must be withdrawn.

Furthermore, as noted, Voges et al. is specifically intended for use in dispensing a physiologically active substance into a user's mouth (without the use of a delivery substrate). Given such a delivery mechanism, there is no motivation or suggestion to use the teachings of Voges in effecting spacing of drops on a delivery substrate. In fact, the proposed delivery mechanism of Voges is antithetical to selecting and achieving a desired spacing of drops. The combination of Voss et al. and Voges thus is inappropriate, and the rejection of claim 3 under 35 U.S.C. §103(a) based on Voss et al. in view of Voges must be withdrawn.

Conclusion

Applicants believe that this application is now in condition for allowance, in view of the above amendments and remarks. Accordingly, applicants respectfully request that the Examiner issue a Notice of Allowability covering the pending claims. If the Examiner has any questions, or if a telephone interview would in any way advance prosecution of the application, please contact the undersigned attorney of record.

Respectfully submitted,

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CERTIFICATE OF FACSIMILE TRANSMISSION

I hereby certify that this correspondence is being facsimile transmitted to Examiner J. Michener, Group Art Unit 1762, Assistant Commissioner for Patents, at facsimile number (571) 273-8300 on December 21, 2005.



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